

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

Plaintiff,

v.

Criminal No. 1:23-cr-10094-PBS

AMY WINSLOW,
MOHAMMAD HOSSEIN MALEKNIA and
REBA DAOUST,

Defendants.

**DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE EVIDENCE REGARDING AND
REFERENCE TO THE THERANOS CASE OR THE FLINT WATER CRISIS**

Defendants Amy Winslow, Mohammad Hossein Maleknia, and Reba Daoust (collectively, the “Defendants”) hereby move *in limine* to preclude the government from offering any evidence regarding or making any reference or comparison to irrelevant, unrelated and prejudicial high-profile blood testing or lead-related cases and events, namely, (1) the now defunct company Theranos, its executives, Elizabeth Holmes and Ramesh Balwani, and their prosecution; or (2) the 2016 water crisis in Flint, Michigan. As grounds therefore, Defendants state (a) that any such reference is patently irrelevant to the claims and defenses in this case; and (b) any potential probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the jury, and wasting valuable trial time.

BACKGROUND

Immediately following the Indictment in this matter, media reports and blogs drew comparisons between the government’s allegations against the Defendants and those made against Theranos and its former Chief Executive Officer, Elizabeth Holmes, and Chief Operating Officer (“COO”), Ramesh Balwani. In 2022, Holmes was convicted in the Northern District of

California of fraud and conspiracy over false claims she made to investors concerning blood testing devices manufactured by Theranos. *United States v. Elizabeth Holmes, et al.*, Case No. 5:18-cr-258 (N.D. Cal.). So was COO Balwani. *Id.* The Theranos case received widespread attention, including through its adoption into various pop culture mediums (including a podcast, book, documentary, and television series). Theranos now stands as a cultural emblem of corporate, medical device fraud. Immediately after the Indictment in this case, reporters began explicitly linking the charges against these Defendants to Theranos. Indeed, one writer went so far as to note that, “Elizabeth Holmes may not be a one-off” and “it sure sounds that, at the core, Magellan was a lot like Theranos.”¹ Another said that “many” have compared this case to the fraud committed by Theranos.²

Media has also inaccurately linked the Defendants to the Flint water crisis. The Flint water crisis stemmed from Flint, Michigan’s decision to switch the source of its drinking water supply, resulting in water quality issues, including increased lead concentrations in the water. The only potential link between Magellan and the Flint water crisis that could potentially exist is if LeadCare Devices were used to conduct venous lead testing in Flint. But the government’s own documents indicate that there were fleetingly few such tests and there is no evidence that the intermittent lead suppression issue impacted any such test. Moreover, the government has not offered—and has, in fact, conceded it will not offer—any evidence that the lead suppression

¹ “Turns out Elizabeth Holmes May Not Be the Only One,” Pink Slip Blog (Apr. 19, 2023), <https://pinkslipblog.blogspot.com/2023/04/turns-out-elizabeth-holmes-may-not-be.html>; see also Amanda Pederson, “The Cost of Greed in Medtech,” Medical Device and Diagnostic Industry Online (June 10, 2024), <https://www.mddionline.com/qa-qc/stop-gambling-on-patient-safety>.

² Marc Fortier, “CEO, Top Execs for Mass. Company Concealed Medical Device’s Inaccurate Lead Tests, Feds Say,” NBC 10 Boston (Apr. 6, 2023), <https://www.nbcboston.com/news/local/ceo-other-top-execs-for-mass-company-concealed-medical-devices-inaccurately-low-lead-tests-feds-say/3014734/>.

issue in the LeadCare Devices caused any individual patient, let alone one associated with the Flint water crisis, to suffer from any medical condition. *See* Dkt. No. 203, Jan. 23, 2025 *Daubert* Hearing Tr. at 79:13–80:18 (government confirming that it does not intend to ask any doctor about “causation” and will only ask them “what they did and when they did it”). Nevertheless, news articles reporting on Magellan and the lead suppression issue with the LeadCare Devices have associated the Company with Flint simply because the devices treat lead exposure and the Flint water crisis is a recent, prominent, serious event involving lead exposure.³

The Defendants anticipate that, following the lead of these publications, the government will attempt to reference and offer evidence at trial regarding these emotionally-charged events that are wholly irrelevant to the charges pending in this case. The government indicated to the Defendants that it will seek to do so and its pre-trial disclosures support that conclusion. For example, the government’s proffered Exhibit List includes six exhibits that pertain to Flint, Michigan. Further, the government seeks to call Dr. Mona Hanna-Attisha, a self-proclaimed “crusading pediatrician who brought the fight for justice in Flint to the national spotlight,” as a non-expert witness who does not appear to have treated any patients whom the government alleges were affected by the lead suppression at issue in this case.⁴

For the reasons set forth below, the Defendants move to exclude any references to Theranos, or Flint, Michigan at trial.

³Julie Applyby, “Thousands of Children Got Tested for Lead with Faulty Devices: What Parents Should Know (June 27, 2024), <https://kffhealthnews.org/news/article/children-lead-testing-doj-settlement-faulty-devices/>.

⁴ <https://monahannaattisha.com/> (last visited January 20, 2025). Dr. Hanna-Attisha’s proposed testimony is also subject to a separate motion *in limine* being filed contemporaneously by the Defendants to preclude the government from offering expert testimony through lay witnesses.

ARGUMENT

I. The Government Should be Barred from Referencing Theranos, or Flint, Michigan at Trial as Irrelevant Under Fed. R. Evid. 402

Evidence is relevant only if: “(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.” Fed. R. Evid. 401. A court must exclude evidence that is irrelevant to the charges. Fed. R. Evid. 401; Fed. R. Evid. 402 (“Irrelevant evidence is not admissible.”).

The government’s anticipated evidence on Theranos and the Flint water crisis, whether offered through exhibits or testimony, fails this simple test. Here, the Defendants have been charged with six counts related to the alleged concealment of a malfunction involving venous tests conducted on LeadCare Devices that purportedly yielded inaccurate lead test results. Based on the evidence in this case, the events surrounding Theranos and the Flint water crisis have no bearing on whether the Defendants are guilty of concealing the alleged malfunction with the LeadCare Devices. In short, these events are irrelevant to any issue at trial. Any such reference or comparison to Theranos or Flint should be precluded on this basis alone.⁵

The government disclosed six exhibits (Government Proposed Exhibit Nos. 351 (attached hereto as Exhibit B), 440 (attached hereto as Exhibit C), 497 (attached hereto as Exhibit D), 504 (attached hereto as Exhibit E), 532 (attached hereto as Exhibit F), 538 (attached hereto as Exhibit G)) and at least one witness—Dr. Mona Hanna-Attisha⁶—that it intends to introduce in this case

⁵ The complete lack of any relevance between Theranos and the current case is underscored by the Government’s proposed Exhibit List, which includes over 570 exhibits – none of which mention or reference Theranos.

⁶ Dr. Mona Hanna-Attisha, a physician, is not a disclosed expert in this case. The government has represented that it intends to elicit testimony from Dr. Hanna-Attisha at trial consistent with her interview report (the “MOI”). Dkt. No. 203, at 100:9–22. [REDACTED]
[REDACTED]. Exhibit A (May 15, 2023 MOI Report of Dr. Hanna-Attisha) [REDACTED]
[REDACTED]

regarding the Flint water crisis. But the LeadCare Devices affected by the lead suppression issue in this case were not used in connection with the Flint water crisis. The lead suppression issue only impacted LeadCare devices that were used to conduct testing on venous samples in BD tubes. LeadCare Ultra was designed for venous samples. While LeadCare II could be used for venous samples, nearly all LeadCare II tests are run on capillary blood samples that use a different kind of tube (a capillary tube) that was not affected by the lead suppression issue. The government's own exhibits make clear that LeadCare Ultra, the device central to the allegations of fraud in this case, was not used for lead testing conducted in connection with the Flint water crisis.⁷ The events in Flint are therefore irrelevant and, thus, inadmissible.

In any event, evidence or mention of the Flint water crisis could only be relevant to any issue in this case if the government could make a threshold showing that: (1) LeadCare Devices affected by the lead suppression issue (or the "Malfunction," as the government refers to it) were used to treat patients connected to the Flint water crisis; and (2) that the lead suppression issue caused harm to a patient. The government has not and cannot make those threshold showings. The government has offered no evidence that an affected device was used in connection with the Flint water crisis, particularly where LeadCare Ultra devices were not used and LeadCare II was almost entirely used to conduct capillary tests, rather than the venous tests affected by the suppression issue. The government has also disclaimed that it will argue that any particular patient experienced harm that was caused by the lead suppression issue. *See* Dkt. No. 203, at 79:13–80:12. Absent this basic showing of relevance, the government should be precluded from offering these exhibits or otherwise referencing the Flint water crisis.

⁷

To the extent the government claims that evidence regarding the Flint water crisis is relevant as “evidence regarding potential harm caused by the Malfunction” that goes to “the materiality” of the alleged fraudulent statement made by the Defendants, that argument fails. *See* Government’s Opposition to Defendants’ Motion to Exclude Expert Testimony of Dr. Adrienne Ettinger and Dr. Courtney Lias, Dkt. No. 192 at *4–5. Without making the threshold showings that affected LeadCare Devices were used or that any harm was caused, evidence related to the Flint water crisis cannot constitute “evidence regarding potential harm.”

With respect to Theranos, the government has offered no basis for its relevance. The Theranos case involved different individuals, devices that are not at issue here and were not even designed for the same purpose, and a completely unrelated set of facts. To date, the only basis the government has articulated for offering evidence related to Theranos is that “the company” (referring to Magellan) made reference to Theranos (the company, presumably) in some of its own documents. The government has not explained whether the Defendants were involved in those documents, what those documents related to, or how any reference to Theranos in the documents could be relevant to this case. Indeed, the Government’s proposed Exhibit List, which includes over 570 exhibits, does not include a single document relating to Theranos. Even if it did, mere reference to another company that made medical devices involving blood testing, in vague, unspecified documents from “the company,” falls far short of establishing that evidence is relevant.

II. Any Reference to Flint or Theranos Should Be Excluded Under Fed. R. Evid. 403 Because it is Unduly Prejudicial

Even if evidence regarding Theranos or the Flint water crisis were relevant, that evidence and any reference to either Theranos or the Flint water crisis should be excluded because the prejudice substantially outweighs any probative value. Both the Theranos case and the Flint water crisis have drawn significant media attention in the last decade. Moreover, both Theranos

and the Flint water crisis provoke strong emotional reactions from those who hear about them, whether they are familiar with the details or not. Therefore, any reference to either Theranos or the Flint water crisis in this case is likely to elicit a strong reaction from jurors that is untethered to the Defendants or the facts of this case. The government seeks to invoke Theranos and the Flint water crisis for exactly this reason—to associate the Defendants and this case with larger issues of wrongdoing and patient harm to appeal to jurors’ emotions, with the hope that it will influence their perception of the Defendants and the Defendants’ conduct as they decide this case. The risk of prejudice is high, and any reference to either Theranos or the Flint water crisis should be excluded.

The Rules instruct the Court to exclude even “relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403. “The term ‘unfair prejudice,’ as to a criminal defendant, speaks to the capacity of some concededly relevant evidence to lure the factfinder into declaring guilt on a ground different from proof specific to the offense charged.” *Old Chief v. United States*, 519 U.S. 172, 180 (1997) (noting that the Advisory Committee Notes define unfair prejudice to include “an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one”).

Despite having different underlying facts, the Theranos case and the Flint water crisis share several characteristics that increase the risk of prejudice here. Both events received widespread media coverage, to the extent that they invaded the popular consciousness. Moreover, both Theranos and the Flint water crisis involve facts that have the tendency to inflame a jury. The events that transpired at Theranos have been widely publicized as an example of serious and pervasive fraud in the medical device industry. The case involves two

convicted company executives who are each serving more than a decade in prison. The Flint water crisis is widely understood to be a mass health crisis involving lead exposure that negatively affected an entire community of largely low income households. Linking the current matter to either of these well-known and emotional events creates the serious risk that the jury would convict the Defendants, not based on guilt, but rather on an “emotional” or otherwise “improper basis,” which Rule 403 squarely bars. *See* Advisory Committee Notes on Fed. R. Evid. 403; *United States v. Varoudakis*, 233 F.3d 113, 122 (1st Cir. 2000). This danger of unfair prejudice substantially outweighs any probative value possibly presented by entirely unrelated events, which, as set forth above, is minimal at best.

Finally, the government should be precluded from referencing these events because it would confuse the issues, mislead the jury, and waste valuable time. This trial is already expected to last at least thirty (30) full days that will span Easter and Passover holidays, as well as a school vacation period. There is no time for an irrelevant side-show, which would serve only to drag out the trial and waste limited judicial resources. *See United States v. Gilbert*, 229 F.3d 15, 23 (1st Cir. 2000). In short, the government has no legitimate reason to reference these events that would squarely compromise the Defendants’ right to a fair trial.

CONCLUSION

For the foregoing reasons, the Defendants respectfully request that this Court issue an order barring the government from introducing evidence (including the exhibits and witnesses identified herein) at trial regarding, referencing, suggesting, or otherwise comparing the underlying events in this case to Theranos, the trials of Elizabeth Holmes and Ramesh Balwani, or the Flint water crisis.

January 30, 2025

Respectfully submitted,

AMY WINSLOW,

By her attorneys,

/s/ William J. Trach

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LOCAL RULE 7.1 AND 112.1 CERTIFICATION

Pursuant to Local Rule 7.1(a)(2) and 112.1, I hereby certify that counsel for the Defendants conferred in good faith with counsel for the government regarding the relief requested in this motion. The government opposes the motion.

/s/ Tara A. Singh

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document filed through the ECF system will be sent electronically by the ECF system to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 30, 2025.

/s/ Tara A. Singh